IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. **NORRIS COCHRAN, *et al*.,** Defendants.	Case No. 8:21-cv-00198

GENESIS HEALTH CARE, INC.'S *AMICUS CURIAE* BRIEF

Pursuant to Standing Order 2018-07, Genesis Health Care, Inc. ("GHC"), by and through its undersigned counsel, respectfully submits this *amicus curiae* brief.[1]

I. INTRODUCTION

On January 22, 2021, Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") filed a complaint in the United States District Court for the District of Maryland against Norris Cochran, U.S. Department of Health and Human Services, Diana Espinosa, and Health Resources and Services Administration. *See Pharma v. Cochran, et al*., 1:21-cv-00198, ECF No. 1. The heart of the case brought by PhRMA is PhRMA's desire to minimize the reach of the 340B Program in spite of Congress' mandate to the contrary. In 1992, Congress enacted the 340B Program to balance the competing interests of high prescription drug prices with the goal of providing affordable medications for those in need. In 2010, to re-balance the competing interests of access to prescription drugs and continually escalating pricing, Congress increased the scope of

[1] Contemporaneously herewith, GHC filed its Motion for Leave to File *Amicus Curiae* Brief (the "Motion"), in compliance with Standing Order 2018-07. As stated in the Motion, no party's counsel in the current action before the Court had any role in this brief and no party's counsel in the current action before the Court contributed money to fund the preparation and/or submission of this brief.

covered entities participating in the 340B program and provided additional specific remedies for the inevitable conflicts that arise in administering such programs. The lawsuit currently before the Court attacks the efficacy of the administrative dispute resolution program ("ADR") Congress enacted to resolve disputes regarding the covered entities that participate in the 340B Program.

In the aforementioned complaint, PhRMA mischaracterizes and misrepresents the facts and results of the *Genesis Health Care, Inc. v. Azar*, 2019 WL 6909572 (D.S.C Dec. 19, 2019) (the "Genesis Case"), which it cited from the article *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 (discussing the Genesis Case) to support PhRMA's allegation that "HRSA often does not terminate covered entities from the 340B Program even where there are findings of serious noncompliance".[2] *See* ECF No. 1, Compl. ¶ 53.

GHC is the plaintiff in the Genesis Case and has a vital interest that the underlying facts presented to the Court are accurately expressed, even when fashioning one's legal arguments to support one's position in the case.[3] GHC wishes to correct PhRMA's misstatements and mischaracterizations of the facts because such misstatements and mischaracterizations have the effect of tainting and disparaging GHC's name, mission, and the trust between the companies GHC partners with and the communities GHC serves. In addressing HHS's ADR rule, PhRMA omitted from its complaint that there were absolutely **no** findings of any compliance violations against GHC, and that HRSA completely voided all audit findings against GHC as well as all conclusions on which the initial findings were based. As explained in further detail below, PhRMA's

[2] "HRSA" is the Health Resources and Services Administration of HHS.

[3] GHC is a nonprofit Federally Qualified Health Center ("FQHC"), as defined in 42 U.S.C. § 1396(l)(2). GHC provides comprehensive primary and preventive healthcare to patients, regardless of their health insurance status and ability to pay, at its facilities throughout South Carolina's Pee Dee Region and in Walterboro, South Carolina.

arguments concerning the Genesis Case (ECF No. 1, Compl. ¶ 53.) are meritless and should be stricken as a matter of law.

II. BACKGROUND: THE GENESIS CASE

In June 2017, the HRSA Office of Pharmacy Affairs ("OPA") conducted a one-and-a-half day on-site audit of GHC to evaluate compliance with the statutory requirements of the 340B Program. 42 U.S.C. § 256b(a)(5)(C). Regarding GHC's compliance with the 340B prohibition on the resale or transfer of drugs, GHC disagreed with the definition of "patient" used by the auditors and their reliance on the employment relationship of the prescribing provider, rather than focusing on the patient's relationship with GHC and whether GHC maintained responsibility of care for treating the patient. GHC, on the other hand, stated that if it was responsible for the care of the patient, as evidenced by the patient being an "active" patient of GHC, the provider that "wrote" the prescription was not relevant to the definition of 'patient." This was particularly important, as GHC employed pharmacists to interact with patients and providers (whether employed by GHC or not) to review and assist with the management of prescription medications for, among other things, adverse interactions, patient understanding, and providing "holistic information" to treating providers. GHC does this because patients are often seen by various providers in different settings, and understanding the medications a patient is taking is vital to the medical decision-making process. "Holistic medication management" in the context of the 340B Program is of paramount importance in managing the healthcare of patients to avoid duplicate medications from multiple providers, to provide patients the opportunity to understand and to assist in the management of their own healthcare, and to comply with the policy decisions made by Congress.

On September 24, 2018, GHC filed suit in the Unites States District Court for the District of South Carolina. The underpinning of GHC's lawsuit was HRSA's definition of the word

"patient" for use in "340B audits." GHC argued that the auditors significantly deviated from the plain language of the 340B statute, which simply requires the patient to be a "patient of the entity." 42 U.S.C. § 256b(a)(5)(B) ("a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.")

GHC successfully argued that Congress did not place any such restrictions on the word "patient," contradicting HRSA's attempts to narrowly define the term beyond the authority granted to them by Congress. On June 6, 2019, in response to GHC's May 2019 amended petition in the Genesis Case, Captain Krista Pedley of HRSA sent a letter to GHC specifically stating that the OPA voided its initial audit findings conducted at GHC on June 21, 2017 through June 22, 2017, voided the accompanying September 24, 2018 revised final audit report to GHC, and voided the March 20, 2019 letter approving GHC's corrective action plan. In fact, Capt. Pedley's letter specifically stated that because the audit findings had been voided, GHC had no further obligations or responsibilities in regard to the audit. *See* June 6, 2019 Letter from Captain Krista Pedley ("HRSA Letter"), attached here to as **Exhibit A**. Thus, HRSA voided its audit findings of GHC because the audit requirements directly contradicted Congress' definition of "patient."

III. PhRMA's MISCHARACTERIZATION OF THE GENESIS CASE

In PhRMA's Complaint filed in this Court, PhRMA challenges the final rule of HHS and HRSA governing 340B disputes through the Administrative Dispute Resolution ("ADR") regulation under 85 Fed. Reg. 80632. *See* ECF No. 1, Compl. PhRMA's Complaint claims that HRSA failed to establish an ADR in a timely fashion and only rushed one into action within weeks of being sued by other entities to do so. Among its claims, PhRMA alleges that this failure created problems of 340B drug diversion and duplication of discounts, allowed covered entities the use of

unlimited contract pharmacies, and failed to precisely define "patient." *Id*. In support of such allegations regarding ADR rulemaking PhRMA claims the following:

> Equally troubling, recent evidence shows that HRSA often does not terminate covered entities from the 340B Program even when there are findings of serious noncompliance. For instance, in one case where HRSA initially concluded that a covered entity had violated 340B requirements, the lack of a clear definition of "patient" hampered its enforcement efforts, and HRSA ultimately withdrew both the enforcement measures and audits. *See* Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO-21-107 (Dec. 2020) ("Dec. 2020 GAO Rep.") (discussing Genesis Health Care Inc. v. Azar, 2019 WL 6909572 (D.S.C. Dec. 19, 2019)), available at https://bit.ly/3c36FGl.

Id. at ¶ 53.

PhRMA not only mischaracterizes the nature and the facts of the Genesis Case, but then uses the Genesis Case as an example of "recent evidence" of "troubling" examples of HRSA failing in its responsibility to deter "diversion." *Id*. PhRMA's mischaracterizations are troubling for many reasons. First, it suggests that GHC was found to have "serious noncompliance." *Id*. PhRMA's allegation insinuates that GHC was in fact found to have violated 340B requirements. However, HRSA enforcement efforts over the definition of "patient" caused HRSA to **void** all its findings against GHC. *See* HRSA Letter, Ex. A. By voiding the audit findings, GHC cannot be characterized in unrelated cases as having violated 340B requirements. PhRMA uses such a mischaracterization to support its allegations that HHS and HRSA are incapable of producing legitimate audits. Instead, what the Genesis Case demonstrates is that GHC was **NOT** in violation of 340B requirements. While the issue of whether HRSA failed to establish ADR or can effectively audit covered entities is a challenge for other parties to take on, GHC should not be unfairly characterized and have its name dragged through unrelated litigation.

Additionally, PhRMA is incorrect by stating that recent evidence shows that HRSA "often" does not terminate covered entities from the 340B Program even when there are findings of serious noncompliance. PhRMA suggests by using the term "often" that the facts of the Genesis Case are a continuing and consistent problem. *See* ECF No. 1, Compl. ¶ 53. To the contrary, the Genesis Case was the first of its kind to challenge audit findings through the courts. Inferring that a first-of-its-kind case is representative of an "often" happenstance is clearly incorrect and misleading to the court. Most importantly, because the audit findings were voided, the Genesis Case cannot be considered an example of noncompliance.

IV. CONCLUSION

GHC respectfully submits this *amicus curiae* brief to provide this Court with an appropriate understanding of the facts in the Genesis Case. PhRMA's allegations regarding the Genesis Case—which are contrary to fact—and PhRMA's arguments specifically regarding the Genesis Case are meritless and should be stricken as a matter of law.

Respectfully submitted,

/s/ Bryan Gales
Bryan Gales (Fed. Bar No. 19671)
NELSON MULLINS RILEY & SCARBOROUGH LLP
100 S. Charles Street, Suite 1600
Baltimore, Maryland 21201
Phone: (443) 392-9400
bryan.gales@nelsonmullins.com

Daniel J. Westbrook
PRO HAC VICE ADMISSION PENDING
NELSON MULLINS RILEY & SCARBOROUGH LLP
1320 Main Street, 17th Floor
Columbia, SC 29201
Phone: (803) 255-9456
dan.westbrook@nelsonmullins.com

James M. Griffin
PRO HAC VICE ADMISSION PENDING
GRIFFIN DAVIS LLC
4408 Forrest Drive, Suite 300
Columbia, SC 29206
Phone: (803) 744-0800
jgriffin@griffinadavislaw.com

J. Keane Mossman
PRO HAC VICE ADMISSION PENDING
GENESIS HEALTH CARE, INC.
3400 West Avenue
Columbia, SC 29203
Phone: (317) 362-6115
keanem@genesisfqhc.org

Attorneys for,
Genesis Health Care, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 14th day of May 2021, a copy of the foregoing was electronically filed via CM/ECF and served on all counsel of record, pursuant to the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Maryland.

/s/ Bryan Gales

Bryan Gales